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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,501	PELTONEN ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 Aug 2008, 5 Jan 2009 and 12 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41,43,44,48,51,52,56,75-77 and 79-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,43,44,48,51,52,56,75,77 and 79-86* is/are rejected.

7)☒ Claim(s) *76* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0808*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is responsive to the Remarks/Arguments filed August 28, 2008 and the claim amendments filed January 5, 2009 and May 12, 2009. In the amendment of January 5, 2009, claims 41, 76-77, and 83-85 were amended and claim 78 was canceled. In the amendment of May 12, 2009, claim 77 was further amended to place the claim in independent form. Claims 41, 43-44, 48, 51-52, 56, 75-77, and 79-86 are now under consideration. Applicant's amendments and arguments have been thoroughly reviewed, but are moot in view of the new grounds of rejection set forth below, which new grounds were necessitated by applicant's claim amendments. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. It is again noted that SEQ ID NO: 3 is a non-elected species and remains withdrawn from consideration (see restriction requirement of October 11, 2006 and the modification to a species election in the Office action of January 29, 2007). The original restriction requirement was traversed in the reply of November 13, 2006. The species election was acknowledged but not traversed in the reply of July 27, 2007. Applicant's remarks of August 28, 2008 note the change from a restriction to a species election, and include a statement that applicants believe the application is in condition for allowance, such that SEQ ID NO: 3 should be rejoined and considered. However,

no generic claim has been allowed in the instant application (in fact, no claims are allowed at the present time). While the examiner concurs that applicant is entitled to consideration of additional species (i.e., SEQ ID NO: 3) upon allowance of a generic claim (as indicated in the action of January 29, 2007), no such claim is allowed at the present time.

Claim Objections Withdrawn

4. Claims 41, 43-44, 48, 51-52, 56, 75-77, and 79-86 were previously objected to because the claims encompass non-elected subject matter (specifically, SEQ ID NO: 3). In view of Applicant's August 28, 2008 comments regarding the possibility of rejoinder, the objection is withdrawn. However, it is again noted that SEQ ID NO: 3 remains withdrawn, as discussed above.

5. It is noted that applicant's claims amendments have overcome the claim amendments set forth in paragraphs 3 and 4 of the Office action of April 2, 2008.

Claim Rejections - 35 USC § 102

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

6. Claim 83 rejected under 35 U.S.C. 102(b) as being anticipated by Birren et al (GenBank Accession No. AC016516, April, 2000).

Claim 83 as amended is drawn to a "purified or isolated polynucleotide of at least 20 nucleotides the complementary strand of which hybridizes under highly stringent conditions to the nucleic acid molecule selected from the group consisting of SEQ ID NO: 3 or SEQ ID NO: 5, wherein said polynucleotide contains the nucleotide at position

324 of SEQ ID NO: 3 or SEQ ID NO: 5". SEQ ID NO: 5 corresponds to the species elected herein. It is noted that the claimed molecule merely requires "at least 20 nucleotides" wherein the complementary strand "hybridizes under highly stringent conditions" and wherein the polynucleotide "contains the nucleotide at position 324 of" SEQ ID NO: 5. Birren et al disclose the *Homo sapiens* chromosome 2 clone RP11-329I10, which includes a sequence identical to instant SEQ ID NO: 5 with the exception of 3 mismatches (see previously provided alignment). The sequence taught by Birren et al includes position 324 and hundreds of nucleotides of flanking sequence on either side thereof (see sequence alignment); thus, one of ordinary skill in the art would readily recognize that the complementary strand in Birren et al's clone would hybridize with SEQ ID NO: 5 under the conditions required by the claim (it is noted that the claim is not drawn to, e.g., a method employing the recited conditions; rather, the molecule must possess the property set forth in the claim). Further, "the nucleotide at position 324" of instant SEQ ID NO: 5 is present in the molecule of Birren et al. Thus, the molecule of Birren et al meets the requirements of the claim.

Claim Rejections - 35 USC § 103

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

7. Claims 41, 43-44, 48, 51-52, 56, 77, and 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren et al (GenBank Accession No. AC016516, April, 2000) in view of Gray et al (US 5,851,769 A [22 December 1998]).

Birren et al disclose the *Homo sapiens* chromosome 2 clone RP11-329I10, which comprises instant SEQ ID NO: 1 (at nucleotides 81,932-82,111; see previously provided alignment), and which also includes a sequence identical to instant SEQ ID NO: 5 with the exception of 3 mismatches (see previously provided alignment).

With regard to claim 41 and claims dependent therefrom, the claims have been amended such that they recite a "nucleic acid molecule comprising SEQ ID NO:1 or the complementary sequence to SEQ ID NO:1, wherein said nucleic acid molecule extends at a maximum 30,000 nucleotides over the 5' and/or 3' end of the nucleic acid molecule of SEQ ID NO: 1". Thus, the molecule of Birren et al comprising SEQ ID NO: 1 does not meet the length limitations of the claim. However, it is noted that the region of Birren et al's molecule that aligns with instant SEQ ID NO: 1 (nucleotides 81,932-82,111) falls within a single contig of 11359 base pairs in length (see the descriptive material appearing before the sequence alignment). The Birren et al reference states that "This is a 'working draft' sequence. It currently consists of 19 contigs. The true order of the pieces is not known and their order in this sequence record is arbitrary". Thus, the Birren et al reference makes clear that the actual order of their contigs has yet to be determined, providing motivation to one of ordinary skill in the art to take further steps to determine that order.

Gray et al disclose methods for the precise physical mapping of genomic DNA (see entire reference). Gray et al teach that their methods provide "an analytic technique to directly map cloned DNA sequences onto individual stretched DNA molecules" (col 14, lines 7-9, as well as col 14 line 52-col 15, line 10) and 'enable

absolute physical mapping of one or several cloned probes in the target genomic interval irrespective of their relative positions" (col 15, lines 3-6). Gray et al disclose that their method allows "construction of kilobase resolution physical maps comprised of minimally overlapping cloned DNA sequences" and teaches the use of their methods to rapidly order contigs (see col 16, line 44-col 17, line 64; see also Example 3). In view of the teachings of Gray et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the molecule of Birren et al so as to have extracted (via, e.g., restriction digestion) the individual contigs of Birren et al, including the 11,359 base pair contig taught by Birren et al that contains instant SEQ ID NO: 1, for use – either directly or following amplification or subcloning -- as probes in the methods taught Gray et al, and in doing so, to have produced a nucleic acid molecule meeting the length requirements of the claims. As the Birren et al reference suggests a need to order the contigs of their clone, and as Gray et al teaches that their method may be used to achieve such ordering of contigs, an ordinary artisan would have been motivated to have made such a modification for the advantage of, and to achieve the predictable result of, rapidly ordering the contigs of Birren et al.

With further regard to claims 43-44, a review of the features of the Birren et al clone indicates that the sequence noted above is genomic DNA; thus, the fragments produced as suggested by the teachings of Birren et al in view of Gray et al will also encompass genomic DNA sequences. Regarding claim 44, it is a property of the genomic DNA sequence suggested by Birren et al in view of Gray et al that it includes "part of a gene," as genes are composed of nucleotides.

Regarding claims 48 and 51-52, Gray et al teach subcloning sequences to be mapped (see, e.g., col 17, lines 1-14, as well as col 16, lines 61-63), and teach the use and propagation of a variety of different types of vectors in compatible host cells (see, e.g., col 11, lines 23-39). Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have subcloned the contig of Birren et al into any of the vectors/host cells taught by Gray et al, and thereby to have produced vectors and cells meeting the requirements of claims 48 and 51-52, for the advantage of, and to achieve the predictable result of, successfully preparing subclones for use in the methods suggested by Birren et al in view of Gray et al.

Regarding claim 77 and claims dependent therefrom (56 and 79-82), claim 77 as amended encompasses any nucleic acid molecule "consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO: 3, SEQ ID NO: 5, or a complementary sequence thereof, wherein said sequence contains the nucleotide at position 324". The molecule suggested by Birren et al in view of Gray et al, whether in restriction fragment/double stranded probe form or in the form of a subclone or amplicon, includes a complementary sequence meeting the requirements of the claims as written. Accordingly, Birren et al in view of Gray et al suggest a molecule meeting the requirements of claim 77. With further to claim 56, the molecule of Birren et al in view of Gray et al could be employed by one of ordinary skill in the art as a "diagnostic composition", such that the references also suggest claim 56. The body claim 56 defines the complete structure of the claimed product ("comprising the nucleic acid molecule of claim 77"), and the preamble statement of the intended use of "for

diagnosing or assessing an individual's predisposition to develop adult-type hypolactasia" is therefore not accorded any patentable weight (see MPEP 2111.02). Regarding claim 79, as the claim is further limiting of the "sequence" of claim 77 (not of the molecule of claim 77), the molecule suggested by Birren et al in view of Gray et al also meets the requirements of claim 79. Regarding claims 80-82, Gray et al further teaches the labeling of molecules to be used as probes in a variety of ways, including both radioactive and fluorescent labels (see, e.g., col 7, lines 25-58, as well as the preferred embodiments discussed at col 21, lines 25-45 and the Examples). As labeled probes are employed in the mapping methods of Gray et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have labeled the probes suggested by Birren et al in view of Gray et al using any of the label types taught by Gray et al to allow for the use of the probes in the ordering of contigs as suggested by the references.

8. Claims 75 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren et al in view of Gray et al, as applied to claims 41, 43-44, 48, 51-52, 56, 77, and 79-82, above, and further in view of Ahern (The Scientist 9:20 [1995]).

The molecules suggested by Birren et al in view of Gray et al are described in the preceding paragraph. The Birren et al and Gray et al references do not teach packaging the molecules suggested by the references into kits, as required by the claims.

Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money (see p. 3/5-4/5). In view of the teachings of Ahern, it

would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Birren et al in view of Gray et al so as to have packaged the molecules suggested by the references into a kit. An ordinary artisan would have been motivated to have made such a modification in order to have provided the molecules to practitioners in a convenient format for the advantages of efficiency and cost-effectiveness.

9. Claims 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren et al in view of Gray et al, as applied to claims 41, 43-44, 48, 51-52, 56, 77, and 79-82, above, and further in view of O'Neill et al (US 6,124,092 [26 Sept 2000]).

The molecules suggested by Birren et al in view of Gray et al are described in the preceding paragraph. The Birren et al and Gray et al references do not teach a primer or primer pair as in claims 84-85. However, it is again noted that Birren et al teach that their sequence is a "working draft" sequence (see Comment section in provided alignment with Accession No. AC016516). Thus, the teaching of Birren et al suggest the need to do additional, confirmatory sequencing of their contigs. Additionally, Gray et al disclose the use of PCR in producing the probes for use in mapping (see, e.g., col 21, lines 24-26). Thus, the Gray et al reference also provides motivation to use PCR in amplifying the contig sequences of Birren et al for use as mapping probes.

O'Neill et al disclose rapid methods for generating and sequencing amplification products (see entire reference, particularly, e.g., col 2, line 64-col 4, line 53). O'Neill et al disclose the use of primers capable of specifically hybridizing to target sequences that are "typically 18-36 nucleotides in length" (see, e.g., col 6, lines 24-56); such

primers are “at least 14 nucleotides” in length, as required by the present claims. It is also noted that claims 84-85 merely require that the claimed primer/primer pair "contains the nucleotide at position 324". The primer of claim 84 and the primer pair of claim 85 must "hybridize under highly stringent conditions" to elected SEQ ID NO: 5; however, the claims do not require any actual fragments or contiguous portions of that sequence (for example, the claims as written do not require a fragment of SEQ ID NO: 5 that includes nucleotide 324 and particular amounts of flanking sequence).

In view of the teachings of Birren et al, Gray et al and O’Neill et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have prepared any primers having the lengths taught by O'Neill et al that could be used in the specific amplification of the molecule suggested by Birren et al in view of Gray et al, and thereby to have produced numerous different primers and primer pairs meeting the requirements of the instant claims. An ordinary artisan would have been motivated to have prepared such primers and primer pairs for the advantage of, and to achieve the predictable result of, confirming the sequence of the contig taught by Birren et al, as suggested by Birren et al's statement that their sequence is a "working draft." Alternatively and/or additionally, an ordinary artisan would have been motivated to have prepared such primers and primer pairs for use in preparing the PCR-amplified probes useful in physical mapping, as suggested by Gray et al.

Conclusion

10. It is again noted that the prior art does not teach or suggest SEQ ID NO: 5. Accordingly, the elected species of claim 76 (i.e., the embodiment directed to an

isolated nucleic acid molecule consisting of SEQ ID NO: 5) is free of the art. However, **Claim 76 is objected to as being dependent upon a rejected base claim**. Additionally, the other, non-elected species embraced by claim 76 (SEQ ID NO: 3) remains withdrawn because no generic claim has been allowed in the instant application, as noted above. Particularly, generic claim 41 (from which claim 76 depends) continues to embrace molecules taught in the prior art, as indicated in the above rejection under 35 USC 103.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571/272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634